An Overview of Relevant Federal and State Laws and Regulations for Community Access Program Consortia[1]

Prepared for the Health Resources and Services Administration

by:

Feldesman, Tucker, Leifer, Fidell & Bank LLP

with the assistance of:

Powell, Goldstein, Frazer & Murphy LLP

April 3, 2001

[1] This document has been prepared for HRSA by the law firms listed above. The U.S. Department of Health and Human Services has not verified the accuracy of data or analysis presented in the document. The opinions expressed in this document are the views of the authors and do not necessarily reflect the official position of the Health Resources and Services Administration or the Department of Health and Human Services. This document is designed to provide accurate and authoritative information in regard to the subject matter covered. It is issued with the understanding that the authors are not engaged in rendering legal or other professional services. If legal advice or other expert assistance is required, the services of a competent professional person should be sought.

I. INTRODUCTION

This issue brief provides an overview of various Federal and State laws and/or regulations that may be relevant to Community Access Program ("CAP") consortia. Specifically, this issue brief summarizes Federal and State laws with which CAP grantees and their counsel should be most familiar in structuring and implementing a CAP arrangement.[2]

II. FEDERAL LAW

There are a number of Federal laws that have important implications for CAP consortia participants. In addition, many states have enacted legislation in a particular area that may differ from or may be more stringent than the Federal law. We have noted instances where CAP participants should be mindful of both the Federal and State laws in a particular area. In all cases, qualified legal counsel should review a proposed arrangement to ensure compliance.

A. Federal Income Tax Law.

CAP participants that are forming a separate entity in order to carry out their program should consider the Federal income tax implications of this decision. There are several key considerations in deciding whether to form a for-profit versus a nonprofit corporation including:

1. the purpose of the corporation (if not charitable, it will not be possible to obtain §501(c)(3) tax-exempt status);

   Note: To the extent that the CAP consortium furnishes only administrative support services to participating providers rather than providing health services, the IRS may not view the activity as "charitable." In addition, if the CAP entity is developing a managed care organization, obtaining Section 501(c)(3) status may be more difficult than in the past since the IRS has been increasingly reluctant to grant exempt status to such organizations.

2. the likely source(s) of capital to finance the entity's operations; and

   Note: To the extent that the corporation will continue to rely on government and/or foundation grants, a tax exemption may be required.

3. the parties' intent regarding the distribution of net income.

Tax-exempt organizations, such as a nonprofit hospital or health center, may ordinarily own a for-profit entity, in whole or in part, without jeopardizing their income tax exemptions, so

[2] This document is designed to provide accurate and authoritative information in regard to the subject matter covered. It is issued with the understanding that the authors are not engaged in rendering legal or other professional services. If legal advice or other expert assistance is required, the services of a competent professional should be sought.

long as the for-profit entity will further the tax-exempt purposes of the (tax-exempt) nonprofit entity. Further, nonprofit entities can invest charitable assets in a for-profit venture.[3] A for-profit entity owned by nonprofit entities may distribute net income to the nonprofit "owners," so long as such revenues are used by the nonprofit owners to further their respective tax-exempt purposes. However, the for-profit entity's "profits" will be taxed before any remaining revenues are paid to the nonprofit owners, typically in the form of dividends.

A limited liability company ("LLC") is sometimes formed to carry out a joint venture between health care providers. An LLC protects its members from liability, similar to a corporation, but is a "pass through" organization for income tax purposes, meaning that the LLC does not pay tax on any income that is passed through to its members. However, unless the LLC itself qualifies for income tax exemption, the income received by a tax-exempt member of the LLC is treated as taxable, un-related business income. Regardless of the form, any separate entity formed by a CAP consortia, whether for profit or nonprofit, should be carefully structured so that the entity does not adversely impact the tax-exempt status of its participants under Federal law.

B. Grant-Related Regulations.

Recipients of Federal grant funds are subject to the responsibilities and requirements that attach to the benefit of receiving these funds. The requirements are in place to safeguard the expenditure of Federal funds and ensure that the recipients are accountable for their use. Depending upon whether the CAP grantee is a nonprofit organization or state/local government, these grant-related requirements may differ. There regulations are set forth in 45 C.F.R. Part 74 (for institutions of higher education, hospitals, and other nonprofit organizations) and Part 92 (state and local governments).

1. *Recordkeeping, Reporting and Monitoring*.

CAP grantees are responsible for managing and monitoring the activities supported by the grant. This includes such requirements as establishing a financial management system that is able to support an accrual accounting system, the accurate identification of the source and application of funds, and the effective control and accountability for all funds, property and assets. Grantees have periodic reporting requirements and any significant deviations from the approved budget and/or project require DHHS's prior approval. A CAP grantee's expenditure of funds is further regulated by the Federal cost principles that govern the allowability of costs charged to grants and that specify the necessary documentation of such

[3] However, if there is a for-profit partner in the venture, the nonprofit entities should be particularly careful that their contributions are fairly valued and that the venture does not come under the control of the for-profit partner. If so, the nonprofit entity (more specifically, its staff and the board of directors that authorized the transaction) could be charged with "giving away" charitable assets and breaching their fiduciary duty to the nonprofit entity. Further, if a tax-exempt entity is controlled by a for-profit entity, the tax-exempt entity will lose its exemption.

costs.[4] Generally, CAP grantees whose grants exceed $300,000 will be subject to the audit requirements described in Office of Management and Budget ("OMB") Circular A-133.

2. *Procurement Standards*.

If the CAP grantee intends to purchase goods or services (e.g. A Management Information System, consultant services, equipment, or clinical services from one or more of the consortium participants) using Federal grant funds, CAP collaborators must ensure that the purchase complies with Federal procurement regulations. Contracts for procuring goods or services which are paid for by Federal funds, in whole or in part, are subject to the administrative requirements and principles contained in OMB Circular A-110[5] as promulgated by DHHS in regulation at 45 C.F.R. Part 74 (for Nonprofits) and Part 92 (for State and Local governments). Specifically, the procurement regulations require Federal grant recipients to: (1) maintain written standards of conduct including an appropriate conflict of interest policy; (2) provide for open and free competition; (3) establish written procurement procedures; (4) maintain procurement records; (5) maintain a contract administration system to ensure conformance with the terms and conditions of the contract; and (6) include certain provisions in the contract.[6] Finally, grantees purchasing goods (or services) in an amount exceeding $100,000 in Federal funds that do not document the need for utilizing a "sole source" procurement must competitively procure the goods (or services) unless their DHHS-approved proposal specifies a specific vendor that will be used.

3. *Property or Equipment Acquired with Federal Funds*.

Property or equipment[7] acquired (or improved), in whole or in part with Federal grant funds may not be encumbered, used for other than approved project purposes, or disposed of without Federal approval.[8] If a CAP grant includes funds for acquisition of property by a grantee or consortium entity, the grantee must have an agreement that incorporates the Part 74 requirements regarding use, sharing or disposition of the property. Further, if the grantee intends

---

[4] See e.g., OMB Cir. A-122 (Cost Principles for Nonprofit Organizations); OMB Cir. A-87 (Cost Principles for State and Local Governments).

[5] Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals and Other Non-Profit Organizations.

[6] The contract must specify, among other things, record-keeping and reporting responsibilities; requirements that the contractor notify and receive prior approval from the CAP grantee in the event that there is a material change in the scope of work (or the approved budget for such services); the contractor's obligation to comply with certain laws and regulations; the circumstances under which the CAP grantee can terminate the contract in case of vendor breach; and procedures by which the CAP grantee will monitor the activities of the contractor. See, 45 C.F.R. § 45 *et seq*.; 45 C.F.R. § 92 *et seq*.

[7] "Equipment" is defined as "tangible nonexpendable personal property, including exempt property, charged directly to the award having a useful life of more than one year and an acquisition cost of $5,000 or more per unit." 45 C.F.R. § 74.2.

[8] See, 45 C.F.R. §§74.32 *et. seq.*

to transfer any property or equipment acquired with Federal funds to another entity, the grantee must first obtain Federal approval and must comply with any disposition instructions that may be provided. These instructions may require the CAP grantee to compensate the Federal government for that percentage of the current fair market value attributable to the "Federal share" in the acquisition or improvement cost of the property or equipment.

C. Intellectual Property Laws.

CAP consortia should consider whether intellectual property law is relevant to their program.[9] As mentioned above, the focus of many CAP collaborations is on the purchase or development of a shared MIS. In other instances, CAPs are premised on the development of shared protocols, policies or procedures. Under all of these circumstances, questions regarding "ownership" of the system or information should be resolved. In general, Federal law protects the unauthorized use and reproduction of "intellectual property" that is owned by others.

Intellectual property laws may affect several activities conducted by CAP collaborations such as negotiating a software licensing agreement that ensures appropriate access to the system (i.e., that enough individuals have access to the software) or that resolves who "owns" the data that is generated by the system; or creating materials such as protocols, health education materials, or manuals that should be copyrighted by the collaborators. Regardless of the particular activity conducted or the intellectual property law involved, CAP participants should clearly define who has rights to use or duplicate the materials, under what terms and conditions, and to whom credit must be given. In some cases, participants who develop a patentable product or invention may need to file appropriate documentation with the U.S. Office of Patent and Trademarks to protect their material or designs.[10] When filing an application, CAP consortia are subject to the regulations that govern patents and inventions developed by nonprofit organizations and small businesses under a Federal grant.[11]

CAP consortia that develop or purchase ownership of intellectual property under a Federal grant award should note that DHHS reserves a royalty-free, non-exclusive and irrevocable right to use, reproduce, and publish the work (or property) for Federal purposes. DHHS may also authorize others to do so.[12]

D. Health Insurance Portability and Accountability Act (HIPAA).

HIPAA[13] was enacted in 1996 and included, among other things, fraud and abuse provisions (i.e. the Medicare Integrity Program), the "Administrative Simplification" provisions that directed DHHS to take steps to increase efficiency in the health care system, and the

---

[9] See e.g., Title 35 of the U.S. Code.
[10] The U.S. Office of Patents and Trademarks grants patents and protects trademarks of individuals and businesses.
[11] See, 37 C.F.R. § 401 *et seq;* See also, 45 C.F.R. § 74 *et seq*.; 45 C.F.R. § 92 *et seq.*
[12] See, 45 C.F.R. § 74.36.
[13] See, Pub. L. No. 104-191 (Aug. 21, 1996).

"Privacy" provisions that directed DHHS to promulgate regulations regarding the security and privacy of health information.

The first set of "Administrative Simplification" rules proposed by DHHS were the Standards for Electronic Transmission.[14] DHHS published the second set of HIPAA regulations, the Standards for Privacy of Individually Identifiable Health Information,[15] commonly referred to as "the Privacy Regulations," on December 28, 2000.[16] The Privacy Regulations cover virtually every health care provider (including hospitals and health centers) and to extend to health plans, and health care clearinghouses. In addition to limiting the circumstances under which personally identifiable patient information can be disclosed (including disclosures within an organization), these Standards impose new administrative requirements for managing and tracking the disclosure of protected patient information.

While health care providers will have time to comply with the HIPAA regulations, they may have significant implications for CAPs that should be addressed prior to their effective date. For example, the Privacy Regulations require in most instances that covered entities obtain patient consent or authorization prior to disclosing individually identifiable health information. Accordingly, CAP collaborators that are purchasing an MIS to share health information must ensure that the system is adaptable to HIPAA standards or it may require modification (and investment) in a matter of months. Moreover, CAP collaborators should ensure that their agreements, whether among themselves or with outside vendors, include clauses that mandate compliance once the regulations go into effect. For additional information regarding HIPAA's privacy considerations, please review the Issue Brief entitled "HIPAA Privacy Considerations for Community Access Program Grantees" dated March 1, 2001, and seek the advice of qualified counsel for specific questions or guidance.

E. Federal Antitrust Law.

In general, Federal antitrust laws[17] prohibit activities among competitors and potential competitors that are considered inherently "anti-competitive" or which are deemed to be anti-competitive when balanced against their potential pro-competitive effects. Activities deemed to be inherently anti-competitive (i.e., per se anti-competitive) include price fixing, boycotting, market allocation agreements, and other forms of collusive behavior. While these activities are per se examples of antitrust law violations, other activities, such as mergers, consolidations and joint ventures, require a careful analysis of the particular facts and circumstances to the law to determine whether potential anti-competitive effects outweigh potential pro-competitive effects. This type of analysis is referred to as the "rule of reason."

---

[14] See, 65 Fed. Reg. 50312 (Aug. 17 2000).
[15] See, 45 C.F.R. § 160 *et seq*.
[16] The effective date of the Privacy Regulations was extended to April 14, 2003. DHHS has accepted additional comments regarding the regulations. At the time of publication, it was unclear whether additional changes would be made to the regulations or the effective date.
[17] The Sherman Act, 15 U.S.C. §§ 1-7 and the Clayton Act, 15 U.S.C. §§ 12-27.

The Federal agencies that enforce the antitrust laws, the Department of Justice ("DOJ") and the Federal Trade Commission ("FTC"), have generally looked favorably upon joint ventures in the health care arena, viewing the majority of them as pro-competitive. However, to provide additional guidance regarding permissible activities, the agencies have created certain "safety zones" which describe particular activities that will not be challenged by DOJ or FTC, absent extraordinary circumstances. These safety zones generally distinguish between activities that may be conducted by "integrated" providers (as specifically defined by the criteria) versus those that may be conducted by "non-integrated" providers.

Any CAP arrangements involving the participation of potentially competing health care providers in the same market or service area should be carefully evaluated to determine whether the collaboration could result in unacceptable levels of market power or other antitrust concerns. For example, a CAP collaboration that seeks to increase access for all populations to specialty care services in a particular county by establishing a shared referral system or appointment schedule and linking providers in the area without shared financial risk may lead to antitrust problems as collaboration without financial integration may be viewed as anti-competitive. This does not mean that the collaboration can not move forward, only that it should be carefully evaluated in order to create a structure that best protects the participants. Many CAP arrangements can be structured to meet the criteria for a safety zone.

State antitrust laws generally mirror the Federal statutes. However, relevant State antitrust laws should be researched independently to determine whether they contain more stringent requirements. In addition, many states have enacted statutes that provide immunity from antitrust prosecution for certain joint venture activities between health care providers that would control health care costs and improve the quality of, and access to, health care services.

F. Federal Fraud and Abuse Law.

The health care fraud and abuse laws[18] present particular challenges when structuring collaborative arrangements among health care providers. Potential sanctions for violating these laws include sizable fines, criminal penalties, and exclusion from the Medicare, Medicaid and other Federal health care programs. Virtually every State has enacted health care fraud and abuse laws that also carry fines and penalties, including criminal sanctions.

1. Federal Anti-Kickback Statute.

The Federal Anti-Kickback statute is designed to prevent fraudulent or abusive arrangements that could result in higher costs to the Government or compromise the quality of care provided to program beneficiaries. Specifically, the Anti-Kickback statute prohibits any person or entity from knowingly or willfully soliciting or receiving (or offering or paying)

[18] Specifically, this refers to the Medicare and Medicaid Patient and Program Protection Act, including its Medicare and Medicaid anti-kickback and false claims and civil monetary penalties provisions (42 U.S.C. §1320a-7, 7a, and 7b); and the Stark Physician Self-Referral Prohibitions (42 U.S.C. §1395nn).

remuneration directly or indirectly, in cash or in kind, to induce patient referrals or the purchase or lease of equipment, goods or services, payable in whole or in part by a Federal health care program.[19]

The implications of the Anti-Kickback statute may be particularly important for CAP consortia because many of the collaborations begin as efforts to increase access for uninsured or underinsured individuals and families by having "deeper pocket" providers helping subsidize the cost of the services provided. In other instances, a "deeper pocket" provider may offer to contribute expensive information systems, personnel, or other resources to facilitate the CAP effort. These arrangements, while well-meaning, may be problematic because the arrangements often include provision for referrals between consortium participants (and those they contract with) and/or presume the purchase of goods or services.

Violations of the Anti-Kickback statute can occur even if the intent to induce (i.e. influence) referrals or a purchase/lease, is only one of several reasons or purposes for the arrangement. CAP consortia must be mindful of the breadth of the statute and ensure that any payment or other "remuneration" that is flowing between the parties not be viewed an unlawful incentive for referrals of Federal health care program beneficiaries or the purchase or lease of goods or services paid for by Federal health care programs. Furthermore, how the parties communicate about the intent of the relationship can dramatically affect exposure under the Anti-Kickback statute. For instance, if one party sends an e-mail to another stating that participating in the CAP collaboration will increase referrals for Medicare or Medicaid patients, this could "taint" the entire relationship.

a. *Safe Harbors*.

In recognition of the fact that not all arrangements between providers are intended to impermissibly induce referrals, a series of statutory and regulatory "safe harbors" have been established to protect certain business practices. In order to be protected under a specific safe harbor rule, the arrangement must meet all requirements of that rule. If an arrangement requires protection under two or more safe harbor rules, it must fully comply with all of the requirements of each of the relevant rules. Arrangements or the purchase or lease of goods or services that do not fit squarely within a safe harbor may still be permissible; each arrangement is judged on a case-by-case basis. Of particular relevance to CAP consortium are the following safe harbors:[20]

> Referral agreements for specialty services:[21] These arrangements will not be viewed as kickback arrangements if: (1) the mutually agreed upon time or circumstance for referral back to a referring practitioner is clinically appropriate; (2) services for which the referral is made are not within the medical expertise of

[19] 42 U.S.C. §1320a-7b.

[20] In addition to the safe harbors discussed below, the OIG has established safe harbors in various other relevant areas. CAP participants should review all safe harbors to determine whether their particular arrangements are permissible.

[21] 42 C.F.R. §1001.952(f).

the referring individual or entity but is within the specific expertise of the practitioner receiving the referral; (3) the parties receive no payment from each other and do not split a global fee from any Federal health care program; and (4) unless both practitioners belong to the same group practice, the only exchange of value between the parties is the remuneration the parties directly receive from third-party payors or from the patient for the services furnished by the particular party.

Investment Interests.[22] An investment interest by providers in an entity providing health care services may be safe-harbored if the investors and the entity meet a number of requirements. The bar for meeting these safe harbor requirements may be lowered somewhat if the investment is located in a geographic area designated as a Medically Underserved Area ("MUA") in accordance with DHHS regulations.

Obstetrical Malpractice Insurance Subsidies:[23] An arrangement in which a hospital or other entity pays for the malpractice insurance premiums of a practitioner who engages in obstetrical practice in a primary care Health Professional Shortage Area ("HPSA") can be safe harbored if certain requirements are met, one of which is that the practitioner be able to maintain that seventy-five percent (75%) of his or her obstetrical patients receiving care under the malpractice insurance coverage reside in a HPSA or MUA or are part of a Medically Underserved Population ("MUP").

Space rental, equipment rental and personal services and management contracts:[24] Agreements for space rental, equipment rental or personal services or management contracts can be safe harbored if there is a written, signed contract between the parties with a term of not less than one year that specifies the premises, equipment, or services to be provided. If services are offered on sporadic or part-time basis, the contract must specify a schedule for such intervals and exact charge for such intervals. The aggregate compensation must be set in advance, consistent with fair market value in an arms-length transaction and can not vary based on volume or value of referrals or business generated between the parties. The aggregate amount of space, equipment or services contracted for cannot exceed what is reasonably necessary to accomplish a commercially reasonable business purpose.

Managed care safe harbor for risk-sharing activities: The OIG has promulgated an interim final rule establishing a safe harbor from prosecution for certain managed care/risk sharing activities.[25] The portion of the rule most relevant to

[22] 42 C.F.R. §1001.952(a).
[23] 42 C.F.R. §1001.952(o).
[24] 42 C.F.R. §§1001.952(b), (c), and (d).
[25] 42 C.F.R. §1001.952(t) and (u).

CAPs protects arrangements between eligible managed care organizations ("EMCO") and the providers or entities with whom they directly contract for the provision of services under a Federal health program (such as Medicaid and Medicare). Without a safe harbor, such an arrangement might be viewed as remuneration (from the provider) in exchange for referrals (from the EMCO). The general rule does not protect these providers or entities, referred to as "downstream contractors," who seek additional payments from Federal health care programs.[26]

b. *Advisory Opinions*.

CAP arrangements that do not meet the requirements of a particular safe harbor under the Anti-Kickback statute may seek an advisory opinion from the OIG. In general, OIG advisory opinions are binding only on the OIG and the party or parties seeking the opinion. This limitation notwithstanding, the opinions often provide insight into the OIG's thinking on enforcement matters.

Recently, the OIG issued several advisory opinions approving transactions traditionally viewed by the OIG as problematic, such as the provision of monetary donations or free or below market goods or services between potential referral sources. While these opinions do not involve parties to a CAP consortium, the justifications for such approvals may be instructive. In short, an arrangement between charitable, mission-driven entities which confers an important "community benefit" to underserved and vulnerable populations and furthers the missions of the participating entities may be permissible under the Anti-Kickback statute, so long as the arrangement does not present a high risk of over utilization of services or increased costs to Federal health care programs and includes safeguards to protect against prohibited referrals. CAP participants should use caution when reviewing these (and other) opinions and should seek legal counsel regarding their interpretation and appropriate application.

2. Federal False Claims Law.

The Social Security Act contains false claims prohibitions applicable to health care benefit programs funded in whole or in part by the Federal government (*e.g.*, Medicare and Medicaid, Maternal and Child Health Program (Title V), Social Services Block Grants (Title XX).[27] Criminal penalties are applicable if an individual knowingly and willfully makes a false statement of material fact in any application for benefits or payments under these programs or if he or she fails to report any sums received to which he or she is not entitled with the intent of

[26]This Safe Harbor provides an exception for health centers seeking wrap-around payments from State Medicaid agencies.

[27] 42 U.S.C. §1395 *et seq.*; 42 U.S.C. §1396a *et seq.*; 42 U.S.C. § 701 *et seq.*; 42 U.S.C. §1367 *et seq*.

fraudulently keeping these sums. Civil penalties also apply if an individual knowingly presents a claim for payment under a Federal health care program and DHHS determines that the individual knows or should have known the claim was false or fraudulent.

Additional Federal legislation prohibits any filing of a false or fraudulent claim against the Federal government.[28] The Federal civil False Claims Act is not limited to fraudulent health care claims, but certainly includes them. Importantly, this law allows a citizen to file a false claims action on behalf of the Federal government. These "*Qui Tam*" or "whistleblower" actions filed on behalf of the Federal government can result in substantial financial reward for the citizen who filed the suit. Common examples of false claims under this law include providers billing for services not rendered; billing for services that are not medically necessary; duplicate billing; unbundling services; filing false cost reports; and upcoding.

CAP network entities that are billing Medicare, Medicaid, or other Federal health care programs on behalf of the CAP's participating providers should be particularly mindful of these provisions. For example, a CAP network entity that purchases and administers a billing system may be liable for the upcoding of a particular provider if the CAP network entity is billing on behalf of the provider. Given the size of the penalties under the Federal laws, CAP entities must be particularly vigilant to minimize any possibility of filing claims that could be viewed as false or fraudulent.

3. Federal Physician Self-Referral Laws.

The Federal "Stark" law prohibits a physician from referring patients for a "designated health service"[29] payable under Medicare or Medicaid to a health care entity if the physician (or an immediate family member) has a direct or indirect financial relationship with the entity. The statute is designed to discourage over-utilization of Medicare and Medicaid services that may occur if a physician is in a position to personally benefit from making referrals for a covered service. In addition, many states have enacted anti-referral laws that place significant limitations on physician "self-referrals" where the services are covered under State health care programs.

Although the Stark law addresses the referral practices of physicians, it operates by prohibiting (unless certain exceptions apply) the health care entity that provides a service pursuant to a prohibited referral from billing Medicare and by denying payment to a State Medicaid agency of the Federal share for a service covered by Medicaid. In addition, co-

[28] 31 U.S.C. §§ 3729-3733.

[29] The "designated health services" subject to the Stark Law are: clinical laboratory services; physical therapy services; occupational therapy services; radiology, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices; home health services and supplies; outpatient prescription drugs; and inpatient and outpatient hospital services.

payments or similar amounts collected from patients, if associated with a prohibited referral, must be refunded.

For purposes of the Stark Law, a physician is treated as a health care "entity," as are health care providers organized as partnerships, corporations, or group practices, etc. Accordingly, the Stark Law can affect CAP participants' ability to bill for services if the referring physician (or an immediate family member of the physician) has a financial relationship with the CAP provider to whom the referral is made.

If an entity has a financial relationship with a physician, it must identify an exception under the statute or regulations that applies to the circumstance. Certain types of financial arrangements are specifically excluded from Stark (e.g., group practices; investments; equipment rentals; bona fide employment relationships; personal services arrangements; rental of office space). In order to be covered by one of these exceptions, arrangements must meet all of the requirements of the exception.

As a general matter, State self-referral laws are frequently more stringent than the Federal standards. CAP participants who are concerned that certain features of their proposed programs may violate the Stark Law should consult qualified legal counsel to determine whether the arrangement is permissible under both Federal and State law.

G. Other Federal Laws.

1. *Section 340B Discount Drug Pricing*.

Certain participants in CAP consortia may be able to access the discount drug pricing program authorized under Section 340B of the Public Health Service Act. Under the terms of the Section 340B Drug Pricing Program, a covered entity (e.g., a Federally qualified health center or a disproportionate share hospital owned by or under contract with a state or local government) is entitled to purchase and pay for covered drugs at favorable prices.[30] The covered entity may operate a pharmacy, subject to the Federal and State restrictions. However, these drugs may be dispensed only to the patients of the covered entity that purchases the drugs. Diversion of the covered drugs to individuals who are not patients of a covered entity constitutes a violation of Section 340B and may subject the covered entity to disqualification from the 340B program, an obligation to pay the discount back to the pharmaceutical manufacturers, and audit by the Federal government.

2. *Federal Tort Claims Act (FTCA)*.

[30] Section 340B of the PHS Act (enacted into law as part of the Veterans Health Care Act of 1992) requires drug manufacturers to enter into agreements with DHHS to provide certain outpatient drugs to "covered entities," including public hospitals and Federally Qualified Health Centers, at prices designed to be, at a minimum, as low as the prices paid by State Medicaid Agencies. See 42 U.S.C. 256b, as amended by Section 602 of P.L.102-585 (November 11, 1992).

Health centers that receive grant funds under Section 330 of the Public Health Service Act have access to medical malpractice coverage for certain employees and contractors under the Federal Tort Claims Act ("FTCA").[31] FTCA only provides medical malpractice coverage for activities which are within the health center's Section 330 scope of project and which are within the scope of the provider's employment agreement or contract. Accordingly, obtaining FTCA coverage for any new services and/or sites (possibly to include CAP-supported activities operated by the FQHC) is dependent upon approval of a change in the health center's scope of project by the Bureau of Primary Health Care ("BPHC"), the agency within DHHS that administers the Section 330 program.

III. ADDITIONAL STATE LAW CONSIDERATIONS.

The above discussion references the applicability of State law "counterparts" that CAP consortia may want to consider. Additional State laws that may potentially affect a CAP consortium include: corporate laws, laws governing licensure (both professional licensure and facility licensure), Certificate of Need laws, employment laws, zoning and even environmental laws if property is acquired or transferred. Moreover, CAP consortia that are seeking to create a managed care organization as part of their collaboration will need to consider the applicability of State insurance laws to determine applicable surplus, net worth or other solvency-related requirements.

A. Incorporation Laws.

Many CAP consortia have had to decide whether to form a separate entity to carry out the program's purposes and, if so, what type of organization to form. If CAP collaborators choose to form a separate entity, it may be structured as a for-profit or nonprofit corporation (See the above discussion of Federal Tax Law), a general or limited partnership, or a limited liability company. CAP participants must consider State incorporation laws in making these determinations. For example, if CAP collaborators choose to form a separate entity in order to protect their own organizations from liability that may result from the CAP program's activities, State laws (and the advantages they may provide) may favor one corporate form over another and should be carefully considered. In all cases, this decision will have important Federal and state tax implications.

B. Licensure and Other Regulatory Issues.

Licensure and related regulatory issues, such as Certificate of Need requirements, may also affect how a CAP collaboration is structured. In particular, collaborations that include the creation of a new health care delivery site, a new type of entity (e.g., managed care organization), or the expansion of a current delivery site to provide a broader array of services are the most likely to be subject to some level of State regulatory oversight. CAP collaborators that assume risk for the services provided under the program, such as an integrated delivery system that contracts with a local HMO, may require a license under State insurance codes. In

[31] See, 42 U.S.C. §233(a).

other cases, CAP consortia that create an entity to receive and track information in order to bill third party payors on behalf of the participants, may fall within the purview of State third party administrator ("TPA") laws. Frequently, State regulatory bodies will require a substantial presentation to demonstrate the entity's qualifications and its ability to comply with the law before granting regulatory approval, licensure, or a Certificate of Need. It is not uncommon for such regulatory approval processes to be time-consuming. Accordingly, early identification of the need for such regulatory approvals is imperative.

C. Community Benefit.

Several states have enacted "community benefit laws" that provide additional funds to entities that provide financial or other community benefits to underserved and vulnerable populations provided that these entities meet specific requirements and can show a benefit to the community. CAP participants should determine whether there are any such community benefit laws that might justify their receipt of such funding which, in turn, will be used to support the community benefits of CAP-arranged services and/or a system to ensure services to underserved populations.

IV. CONCLUSION

This issue brief provides an introduction to highly complex areas of Federal and State law. Each CAP consortium is different from the next and the relevance of some or even most of these laws will vary considerably. The goal of this overview is to heighten the reader's sensitivity so that issues may be identified early on and appropriately addressed.